

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PLEXXIKON INC.,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

Case No. [17-cv-04405-HSG](#)

**ORDER DENYING MOTION TO
EXCLUDE TESTIMONY OF DR.
MICHAEL L. METZKER**

Re: Dkt. No. 200

Pending before the Court is Defendant Novartis Pharmaceuticals Corporation's motion to exclude the testimony of Plaintiff Plexxikon Inc.'s expert Dr. Michael L. Metzker. *See* Dkt. No. 200. The Court held a hearing on November 1, 2019. Dkt. No. 337. For the reasons detailed below, the Court **DENIES** the motion.

I. BACKGROUND

Issues of patent invalidity and infringement are determined from the perspective of a person of ordinary skill in the art ("POSITA") in the field of the claimed invention. *See, e.g., Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361, n.3 (Fed. Cir. 2008). Despite the parties' myriad disagreements in this action, they appear to agree that in this case the pertinent art is "synthetic organic chemistry" or "medicinal chemistry." *See* Dkt. No 228 at 7 (citing 200-06 at ¶ 7); *see also* Dkt. No. 343 ("Tr.") at 70:8–74:10. Additionally, they agree that a POSITA in this case:

would have a Ph.D. or equivalent degree in organic or medicinal chemistry and 2–3 years of post-graduate experience working in medicinal chemistry, synthetic organic chemistry, and/or kinase chemistry, including the development of potential drug candidates. A person of ordinary skill in the art would also include a person who has a Bachelor's or Master's degree in organic chemistry or medicinal

chemistry if such a person had more years of experience in medicinal chemistry and/or the development of potential drug candidates.

See id.

In the pending motion to exclude, Defendant does not challenge the substance of Dr. Metzker's opinions or testimony. Rather, Defendant argues that based on his educational background and experience, Dr. Metzker is not a POSITA, and therefore is unqualified to serve as an expert in this case. *See* Dkt. No. 200.

II. LEGAL STANDARD

Federal Rule of Evidence 702 allows a qualified expert to testify "in the form of an opinion or otherwise" where:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Expert testimony is admissible under Rule 702 if it is both relevant and reliable. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). "[R]elevance means that the evidence will assist the trier of fact to understand or determine a fact in issue." *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007); *see also Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) ("The requirement that the opinion testimony assist the trier of fact goes primarily to relevance.") (quotation omitted).¹ Under the reliability requirement, the expert testimony must "ha[ve] a reliable basis in the knowledge and experience of the relevant discipline." *Primiano*, 598 F.3d at 565. To ensure reliability, the Court "assess[es] the [expert's] reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance." *Id.* at 564.

III. DISCUSSION

Defendant raises a threshold legal question of whether Dr. Metzker must be a POSITA to

¹ Whether to admit expert testimony is evaluated "under the law of the regional circuit," so in this case, under the law of the Ninth Circuit. *See Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1391 (Fed. Cir. 2003).

offer expert testimony in this action. Citing the Federal Circuit’s opinion in *Sundance v. Demonte Fabricating Ltd.*, Defendant urges that it would be an abuse of discretion to permit Dr. Metzker to testify as an expert if he were not a POSITA. *See* 550 F.3d at 1360–65. Defendant then argues that despite agreeing to Defendant’s definition of a POSITA, Dr. Metzker does not in fact meet this definition. Plaintiff disputes both Defendant’s legal premise and its factual evaluation of Dr. Metzker’s qualifications. The Court addresses each argument in turn.

A. Expert Testimony under Rule 702

In *Sundance, Inc. v. Demonte Fabricating Ltd.*, the Federal Circuit considered the admissibility of expert testimony offered by a patent attorney on noninfringement and invalidity. 550 F.3d at 1364–65. The court observed that the defendant, the proponent of the testimony, had failed to explain how the attorney was an expert in the pertinent art of “tarps or covers.” *Id.* at 1362. The court noted that the attorney “ha[d] no experience whatsoever” in this field, and that the defendant had also failed to establish that the attorney’s actual experience was otherwise “sufficiently related” to this field. *Id.*

The court concluded that as a result, the attorney could not “assist the trier of fact” and was unqualified to offer expert testimony on the topic of invalidity. *Id.* (citing Fed. R. Evid. 702). To find otherwise, the Federal Circuit noted, would “serve[] only to cause mischief and confuse the factfinder.” *Id.* In summary, the court explained:

We hold that it is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement or invalidity unless that witness is qualified as an expert in the pertinent art. Testimony proffered by a witness lacking the relevant technical expertise fails the standard of admissibility under Fed. R. Evid. 702.

Id. at 1363. Defendant points to this language as a “bright line rule,” which creates a floor for admitting any expert testimony under Rule 702 in patent cases. *See* Dkt. No. 200 at 4.

Plaintiff, in contrast, points to the Federal Circuit’s opinion in *SEB S.A. v. Montgomery Ward & Co.*, arguing that it reaffirms that Rule 702 governs the admissibility of expert testimony in patent cases rather than the parties’ definition of a POSITA. 594 F.3d 1360, 1373 (Fed. Cir. 2010), *aff’d sub nom. Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011). In *SEB*, the

Federal Circuit determined that the district court did not abuse its discretion by admitting expert testimony on infringement in a patent dispute involving a deep fryer, despite the fact that the expert “testified that he [wa]s not skilled in designing deep fryers.” *Id.* at 1373. The Court reasoned that the expert nevertheless “had sufficient relevant technical expertise for the district court to allow him to testify” because:

Although [the expert] testified that he is not skilled in designing deep fryers, [he] explained that his experience was relevant because the claimed invention ‘involves the selection of particular . . . polymer material that have certain characteristics’ and that ‘[m]ost of the areas [he has] worked in . . . have used polymers in one form or another.’ . . . [The expert’s] testimony established an adequate relationship between his experience and the claimed invention.

Id. Rather than suggesting that *Sundance* declared a sea change in the admissibility of expert testimony in patent cases, the Federal Circuit in *SEB* quickly dismissed any comparison, stating that “[t]his case comes nowhere close to the unusual situation in [*Sundance*]” in which the Court “held that a district court abused its discretion when it admitted the testimony of a patent law expert ‘[d]espite the absence of any suggestion of relevant technical expertise.’” *Id.* (citing *Sundance*, 550 F.3d at 1361–62). The Federal Circuit further noted that “[d]istrict courts enjoy ‘wide latitude’ to determine admissibility,” and “the district court was in the best place to judge that [the expert] had the ‘knowledge, skill, experience, training, [and] education’ of a ‘specialized’ nature that was likely to ‘assist the trier of fact to understand the evidence or to determine’ infringement.” *Id.* (quoting Fed. R. Evid. 702).

Unfortunately, the Federal Circuit has given little additional guidance on the import of *Sundance*. It is, therefore, unsurprising that district courts have reached different conclusions about whether being a POSITA is a threshold requirement to testify as an expert in patent cases. Compare *CardioNet, LLC v. ScottCare Corp.*, No. CV 12-2516, 2017 WL 4742476, at *3 (E.D. Pa. Oct. 19, 2017) and *Asetek Danmark A/S v. CMI USA, Inc.*, No. 13-CV-00457-JST, 2014 WL 5590699, at *2 (N.D. Cal. Nov. 3, 2014), with *Morpho Detection, Inc. v. Smiths Detection, Inc.*, No. 2:11CV498, 2012 WL 6004085, at *1–2 (E.D. Va. Nov. 30, 2012) and *Bow Jax, Inc. v. Sims Vibration Lab., Inc.*, No. 09-CV-47-RMP, 2011 WL 13228396, at *2–3 (E.D. Wash. Apr. 6,

2011).

However, the Court is not persuaded that this is the “unusual situation” that the Federal Circuit had in mind when deciding *Sundance*. See *SEB*, 594 F.3d at 1373. As explained in more detail below, it is undisputed that Dr. Metzker has a bachelor’s degree in biochemistry and biophysics, and a Ph.D. in molecular and human genetics. See, e.g., Dkt. No. 228-3, Ex. 2 (Dr. Metzker’s Curriculum Vitae). This is not the kind of “junk science” that the Court has a gatekeeping duty to exclude. See *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1197 (9th Cir. 2014). Nor is it akin to *Sundance*, in which the Federal Circuit cautioned that “[a]llowing a patent law expert without any technical expertise to testify on the issues of infringement and validity amounts to nothing more than advocacy from the witness stand.” 550 F.3d at 1364–65; cf. *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1296 (Fed. Cir. 2012) (“In *Sundance* this court held that it was an abuse of discretion to permit *an attorney* to testify as an expert on issues of infringement and validity, when the attorney was not qualified as an expert in the technical subject matter.” (emphasis added)). There is no question here that Dr. Metzker is a scientist, not a patent attorney.

Moreover, the Federal Circuit in *Sundance* appeared to go out of its way to note that it was not altering the *status quo*. It emphasized that “[t]here is, of course, no basis for carving out a special rule as to experts in patent cases.” *Id.* at 1360. Rather, “[a]dmission of expert testimony [in the context of patent cases] remains subject to the Rules of Evidence and is committed to the discretion of the district court.” *Id.* (quotations omitted). The Court finds it unlikely that the Federal Circuit would emphasize the significance of the district court’s discretion in admitting expert testimony on the one hand, while simultaneously placing a new and significant limitation on that discretion on the other. Cf. *Whitman v. Am. Trucking Ass’n*s, 531 U.S. 457, 468 (2001) (noting that Congress “does not . . . hide elephants in mouseholes”). In any event, the Court finds that the Federal Circuit’s reasoning in *SEB* is far more applicable to this case than *Sundance*. And as was the case in *SEB*, the Court finds that Dr. Metzker has sufficient relevant technical expertise. *SEB*, 594 F.3d at 1373.

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B. Dr. Metzker's Qualifications

Moreover, even assuming the Federal Circuit's opinion in *Sundance* requires the Court to find that Dr. Metzker is a POSITA, the Court finds in the alternative that Dr. Metzker satisfies the parties' agreed-upon definition. The Court acknowledges, however, the unusual circumstances presented here, where Plaintiff appears to have agreed to a POSITA definition that leaves Dr. Metzker susceptible to challenge on this basis. Rather than proffer a definition that unquestionably includes Dr. Metzker's educational background and experience, Plaintiff devotes over five pages of its opposition brief to explaining why Dr. Metzker's education and experience are equivalent to or otherwise sufficient under the definition. *See* Dkt. No. 228 at 8–13; *see also* Tr. at 70:8–72:20. The Court need not understand Plaintiff's litigation strategy on this point, but as a result, the Court must look in detail at Dr. Metzker's qualifications and evaluate the parties' dueling expert declarations.

In doing so, the Court finds that Dr. Metzker meets the secondary POSITA definition agreed on by the parties:

A person of ordinary skill in the art would also include a person who has a Bachelor's or Master's degree in organic chemistry or medicinal chemistry if such a person had more [than 2–3] years of experience in medicinal chemistry and/or the development of potential drug candidates.

See Dkt. No 228 at 7 (citing 200-06 at ¶ 7). As an initial matter, the Court agrees with Plaintiff that the *title* of the degree from a university is not dispositive. Confirming whether an expert is a POSITA is not an exercise in formalism.

Here, Dr. Metzker has a bachelor's degree in biochemistry and biophysics from the University of California, Davis. *See* Dkt. No. 228-3, Ex. 2. However, he credibly explained that medicinal chemistry is an *application* of the biochemistry degree he received. *See* Dkt. No. 228-13 ("Metzker Decl.") at ¶ 6. Defendant's own citations support this conclusion. *See* Dkt. Nos. 200-35, Ex. 33 (listing "[m]edicinal chemistry" as a possible career area for those with degrees in biochemistry); 200-21, Ex. 19 (listing biochemistry as a "Technical Discipline" and medicinal chemistry as an "Applied Area of Chemistry"). Dr. Metzker further explained that as part of his

coursework he “was educated in biochemically active compounds, the study and kinetics of their metabolism, their mode of action at the molecular level, and relationships between the chemical structures of molecules and their biochemical activity.” Metzker Decl. at ¶ 6. He also studied kinase inhibition as part of his undergraduate degrees. *Id.*

In response, Defendant argues that this is inapposite because biochemistry and biophysics are distinct fields from organic and medicinal chemistry. *See* Dkt. No. 200 at 11–12. In support, Defendant points to various websites, including the American Chemistry Society’s “College to Career” webpage, as well as exemplar textbooks. *See, e.g., id.*; Dkt. Nos. 200-21, Ex. 19; 200-24, Ex. 22; 200-26, Ex. 24; 200-27, Ex. 25; 200-29, Ex. 27; 200-30, Ex. 28. Defendant also relies heavily on a declaration from one of its own experts, Dr. Phil Baran.² *See* Dkt. No. 200-1 (“Baran Decl.”) at ¶¶ 49, 58; *see also* Dkt. No. 236-2, Ex. 1 (“Baran Rebuttal Report”).

But the Court is not persuaded by Defendant’s formalistic arguments. Defendant’s own citations belie the firm distinction it attempts to draw between these fields: The Nature.com webpage that Defendant cites, for example, explains that “[o]rganic chemistry is the study of the synthesis, structure, reactivity and properties of chemical compounds primarily constructed of carbon.” *See* Dkt. No. 200-27, Ex. 25 at 1. However, the next sentence states that “[a]ll life on earth is carbon-based, thus organic chemistry is also the basis of *biochemistry*.” *See id.* (emphasis added); *see also* Dkt. No. 200-28, Ex. 26 at 1 (same). Similarly, the Wikipedia page that Defendant cites for the description of medicinal chemistry notes that this is “interdisciplinary” and that practitioners may have degrees in other fields. *See* Dkt. No. 200-32, Ex. 30 at 1, 3 (“[M]ost entry-level workers in medicinal chemistry, especially in the U.S., do not have formal training in medicinal chemistry.”).

Looking at the course catalog for the University of California, Davis further underscores the problem with Defendant’s approach: the institution does not appear to have offered a bachelor’s degree in either organic chemistry or medicinal chemistry when Dr. Metzker was in

² The Court recently granted in part Plaintiff’s motion to strike Dr. Baran’s declaration, including ¶¶ 33–35, 38–40, 42–46, 50–57, so the Court only looks to those remaining paragraphs. *See* Dkt. No. 392.

attendance. *See* Dkt. No. 200-41. Ex. 39. And the coursework for “chemistry” and “biochemistry,” two degrees that the school did offer, are quite similar. *Compare id.* at 153–54 (requirements for B.S. in biochemistry), *with id.* at 160–61 (requirements for B.S. in Chemistry). Defendant counters that “[t]hese two majors have different requirements and confer different skill sets geared toward different career goals.” *See* Dkt. No. 244 at 13. Yet Defendant offers no authority for this blanket assertion. In short, other than a cursory explanation that the definitions of the fields of biochemistry on the one hand and organic chemistry and medicinal chemistry on the other are different, Defendant raises no substantive arguments as to why a degree in biochemistry cannot be considered equivalent to organic or medicinal chemistry.

Dr. Metzker also has far more than the two to three years of postgraduate experience that he needs in development of potential drug candidates to be considered qualified as a POSITA. *See* Dkt. No 228 at 7 (citing 200-06 at ¶ 7). Dr. Metzker testified at his deposition that during his time at Baylor College of Medicine, he synthesized a number of inhibitors of polymerases that are involved in the replication of diseases, and that some of those molecules were intended to be therapeutic drugs. *See* Dkt. No. 228-2 (“Metzker Depo. Tr.”) at 13:25–17:10. Dr. Metzker also explained that during his three years at Merck & Co. he “was involved in the identification of drug targets.” *See id.* at 17:13–21:9; *see also* Metzker Decl. at ¶ 10. And as a professor at Baylor College of Medicine and Rice University, beginning in 1999 and 2001 respectively, Dr. Metzker’s work involved designing, synthesizing, and testing new modified nucleosides and nucleotides to use as inhibitors for DNA polymerase for potential new drug therapies. *See* Metzker Decl. at ¶ 11; *see also* Metzker Depo. Tr. at 21:10–23:16, 24:24–26:5. Although Dr. Metzker’s work did not specifically involve kinase inhibitors, the POSITA definition is not limited to medicinal chemistry experience in or drug development of kinase inhibitors. *See* Dkt. No 228 at 7 (citing 200-06 at ¶ 7). In any event, Dr. Metzker has explained how the molecules that he developed are similar in structure to kinase inhibitors, and in some instances may be inhibitors to *both* DNA polymerase and kinase. *See* Metzker Decl. at ¶ 12.

Defendant raises several concerns that Dr. Metzker’s experience is not as extensive as it may first appear. Defendant points out that Dr. Metzker worked on teams with other chemists

1 who may have performed the actual, relevant work and that Dr. Metzker was unable—either
2 during his deposition or in his declaration—to provide more detail about the nature of his work.
3 *See* Dkt. No. 244 at 7–9. Defendant suggests that to be considered a POSITA, Dr. Metzker had to
4 quantify the number of potential drug candidates he worked on or provide “laboratory notebooks,
5 assay reports, memoranda, meeting minutes, progress reports, or other records” to explain the
6 nature of his work. *See id.* Defendant cites no authority to support its argument that an expert
7 must chronicle his multi-decade career through detailed notebooks or meeting minutes to testify at
8 trial, and the Court declines to adopt such a strained construction here.


9 The Court understands that Defendant believes Dr. Metzker’s experience is primarily as a
10 microbiologist. *See id.* at 6. However, the Court declines to credit Defendant’s speculation that
11 Dr. Metzker has embellished his qualifications. Defendant will have the opportunity at trial to
12 question the relative strength of Dr. Metzker’s qualifications and to contrast them with the
13 qualifications of Defendant’s own experts. But the Court need not determine which experts are
14 better credentialed or more persuasive for purposes of this *Daubert* motion.

15 **IV. CONCLUSION**

16 The Court finds that Plaintiff has sufficiently demonstrated that Dr. Metzker has the
17 relevant knowledge, skill, experience, training, and education to qualify him as an expert in this
18 case. *See* Fed. R. Evid. 702. Accordingly, the Court **DENIES** the motion to exclude Dr. Metzker.

19 **IT IS SO ORDERED.**

20 Dated: 3/25/2020

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22 HAYWOOD S. GILLIAM, JR.
23 United States District Judge
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